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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,532	12/10/2001	George J. Picha	29462	7870
116	7590	12/18/2003	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 12/18/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/016,532

Applicant(s)

PICHA ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-15, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 16-17 is/are rejected.
- 7) ☐ Claim(s) 4-6 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group I, species 1 in Paper No. 4 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7,10-15,18-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Upon allowance of a generic claim, the dependent non-elected claims may be considered at the time of allowance. See paper no. 3.

With respect to the rejoinder of process claims, process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03).

An action on the merits will now follow.

### *Specification*

The abstract of the disclosure is objected to because it is too long. Applicant is requested to amend it to 150 words. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: brief description to fig. 12 is missing.

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Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1,3,8,16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said casing " in line 12. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether applicant intended "said constraining member" instead.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor (U.S. Patent No. 5,279,564)

Taylor discloses a device comprising a tubular portion , an internal bolster having a radial wing 12,22 and permitting a first and second orientation. And a constraining member 14 which encases the bolster. ( See figures 1-6.) Lacking any

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structurally distinguishing features, the Examiner is construing the tubular element of 14 to be a capsule.

Claims 1,3 are rejected under 35 U.S.C. 102(b) as being anticipated by Semrad (U.S. Patent No. 4,986,810)

Semrad discloses a device comprising a tubular portion , an internal bolster having a radial wing 14,15 and permitting a first and second orientation and further comprising a constraining member which encases the bolster. ( See figures 1-11). Lacking any structurally distinguishing features, the Examiner is construing the tubular element of 14 to be a capsule.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Picha et al. ( U.S. Patent No. 5,941,855).

Picha et al. disclose the device as claimed. See figures 1-12. The constraining member is considered to be the suture wrap 37.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (U.S. Patent No. 5,279,564) in view of Parks ( U.S. Patent NO. 4,685,901).

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See Taylor or above. Taylor discloses the claims as substantially claimed .

Taylor discloses a stop ring 18. However, Taylor does not disclose the specifics of a locking ring as claimed ( claim 16) . Parks discloses a device in the analogous art with a bolster ( balloon) and a locking ring as specifically claimed by applicant in claim 16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute/modify the locking ring of Taylor with the locking ring of Parks as a mere substitute of rings which function in the same manner wherein the locking ring would provide the same function of securing the device to the patient's body.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Picha et al. (U.S. Patent No. 5,941,855) in view of Parks ( U.S. Patent NO. 4,685,901).

See Picha et al. above. Picha et al. disclose the claims as substantially claimed . However, Picha does not disclose a locking ring as claimed ( claim 17) . Parks discloses a device in the analogous art with a bolster ( balloon) and a locking ring as specifically claimed by applicant in claim 17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Picha et al. with a locking ring as taught by Parks which permit air to contact the entry to the stoma to reduce infection and skin irritation and further provide a better securement to the patient's body.

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***Allowable Subject Matter***

Claims 4-6,9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT